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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,756	11/06/2002	Gregory Paul Handreck	Faulding/1CON	6753

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FISH & NEAVE  
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NEW YORK, NY 10020-1105

EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/18/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/042,756

Applicant(s)

HANDRECK ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/773,480.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

Receipt is acknowledged of the Preliminary Amendment A and the Petition, received by the Office November 6, 2002 and January 17, 2003, respectively.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Us Patent 6,160,165 to Shinal in view of Us Patent 5,167,816 to Kruger *et al.* OR US Patent 6,274,635 to Travis OR Us Patent 6,174,873 to Wrenn. Shinal teaches a method for the preparation of disodium pamidronate. The method comprises addition of aqueous sodium hydroxide to a stirred slurry of pamidronic acid in an about 2:1 molar ratio of NaOH to acid, optionally comprising excess mannitol, to yield a clear solution of pH 6.5+/- 0.1 (column 1, lines 62-66). a stirred slurry of pamidronate in water, (2) adding a solution of sodium hydroxide to give a clear solution at pH of about 6.5.

Shinal does not teach that the solution is packaged in solution form, but instead teaches that the solution be dried prior to packaging.

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Kruger *et al.* teaches that it is known in the medical art to use standard glass vials to contain medical solutions. Additionally, Kruger *et al.* teach that flexible plastic bags are also known to contain drug solutions (column 3, lines 36-46).

Travis discloses pharmaceutical methods and compositions. More specifically, Travis teaches that the composition of their invention can be a parenteral formulation such as injectable solutions and suspensions. Additionally, Travis teaches that solutions and suspensions are generally provided in a sealed ampule or vial (column 23, lines 53-63).

Wrenn discloses oral pharmaceutical dosage forms. More specifically, Wrenn teaches that the various oral dosage forms can be prepared according to conventional procedures. Wrenn is relied upon for teaching that liquid dosage forms may be supplied as a made up vial, or may be supplied in a lyophilized state for dilution just prior to administration (column 17, lines 12-17).

It is the position of the examiner that based on the teachings of the three secondary references listed above, it is well known in the art to package drugs in liquid form, in either vials, or flexible plastic bags. One of ordinary skill in the art would be motivated to package the liquid slurry disclosed by Shinal in a vial or bag, such as those taught by the secondary references. Furthermore, the drug discussed by both applicant and Shinal is administered in liquid form. Shinal simply dries it, then reconstitutes it prior to administration. Wrenn teaches that liquid dosage forms are known to be stored in a vial, or in a lyophilized phrase for dilution just prior to administration. Therefore, Wrenn teaches that it would be obvious to do either (liquid storage, or lyophilized storage for reconstitution) with a drug to be administered in liquid form. The expected result would be a successful dosage form. Therefore, this invention as a whole would

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have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam  
Patent Examiner  
Art Unit 1615  
June 13, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600